APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Mohan Krishnan et al.	Examiner: Joseph A. Stoklosa
Serial No.: 10/731,421	Group Art Unit: 3762
Filed: December 09, 2003	Docket: 279.650US1

For: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
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The Appeal Brief is presented in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed on November 10, 2009 and further in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on October 8, 2009, from the Final Rejection of claims 1, 5, 7, and 9-18 of the above-identified application, as set forth in the Final Office Action mailed on July 8, 2009.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Cardiac Pacemakers, Inc. as evidenced by the Assignment recorded at Reel 015220, Frames 0685-0689.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 9, 2003 with claims 1-23. During prosecution claim 24 was added and claims 6 and 21-24 were canceled.

Claims 2-4, 8, 19, and 20 are presently withdrawn.

A Final Office Action (hereinafter "the Final Office Action") was mailed July 8, 2009. Claims 1, 5, 7, and 9-18 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated July 8, 2009.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present inventive subject matter include, but are not limited to, an endocardial lead for a left heart chamber.

INDEPENDENT CLAIM 1

1. A lead (100) comprising:

a lead body (102) extending from a proximal end to a distal end; (Figure 1; page 2, lines 19-20) and

a ring electrode (216) coupled to the lead body; (Figure 3; page 3, lines 25-26);

wherein the lead body and the ring electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface (510) of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, (Figure 5; page 6, lines 1-20); and wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres (Figure 3; page 5, lines 1-10).

INDEPENDENT CLAIM 11

11. A lead comprising:

a lead body (102) extending from a proximal end to a distal end; (Figure 1; page 2, lines 19-20) and

a ring electrode (216) coupled to the lead body; (Figure 3; page 3, lines 25-26);

wherein the lead body has a textured outer surface (510) adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; (Figure 5; page 6, lines 1-20); and

wherein the ring electrode includes an outer textured surface including titanium microspheres. (Figure 3; page 5, lines 1-10).

INDEPENDENT CLAIM 17

17. A lead comprising:

a lead body (102) extending from a proximal end to a distal end; (Figure 1; page 2, lines 19-20)

a ring electrode (216) coupled to the lead body; (Figure 3; page 3, lines 25-26); and

means for passively preventing formation of clots on the ring electrode and the lead body, wherein means for passively preventing clots on the ring electrode includes a titanium microsphere outer surface coating on at least a portion of the ring electrode, (Figure 3; page 5, lines 1-10); and wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface (510) of the lead body when exposed to a bloodstream. (Figure 5; page 6, lines 1-20);

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to each of the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

§ *103 Rejection of the Claims*

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Thoren (U.S. 4,149,542) in view of Helland et al. (U.S. 5,318,572; hereinafter "Helland").

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Thoren in view of Helland and in view of MacGregor (U.S. 4,280,514).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.*

The M.P.E.P. adopts this line of reasoning, stating that

> In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and

not based on Appellant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

Moreover, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP § 2143.01.

B) Discussion of the rejection claims 1, 5, 7, and 9-18 which were rejected under 35 U.S.C. § 103(a) as being obvious over Thoren (U.S. 4,149,542) in view of Helland et al. (U.S. 5,318,572; hereinafter "Helland").

Claims 1, 5, 7, 9, and 10

Appellant believes claim 1 is not obvious in view of the cited references since, even if combined, the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the cited combination: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1.

In contrast, Thoren discusses a lead with a side component 5 which is receptive to tissue ingrowth. (Col. 3, lines 15-34). Thoren does not discuss the lead body itself. Likewise, Helland discusses a lead with the electrode tip having spheroidal particles 70 for chronic ingrowth of tissue. (Col. 6, lines 5-8). Helland discusses that lead body 22 is "preferably fabricated of silicone rubber, polyurethane or other suitable biocompatible, biostable polymer." (Col. 4, lines 8-10). Accordingly, neither reference suggest or discusses "a lead body adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream," as recited in claim 1.

In the Advisory Action dated September 21, 2009, the Examiner asserts that Helland discusses "microspheres allowing a layer of blood cells to form as blood passes through the pores created by the microspheres." (Page 2 of Advisory Action). However, the microspheres of the Helland reference are located on the electrode tip, they are not on the "lead body," as recited in claim 1. The Thoren reference does not overcome this deficiency. In the Thoren reference, the side component 5 is not the "lead body." Accordingly, claim 1 is not obvious in view of the

cited references since, even if combined, the combination does not include or suggest: "a lead body adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream," as recited in claim 1.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 11-16

Appellant believes claim 11 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the combination: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11.

As discussed above, the references, both singly and in combination, do not include such subject matter.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 17 and 18

Appellant believes claim 17 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the combination: wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17.

As discussed above, the references, both singly and in combination, do not include such subject matter.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

C) Discussion of the rejection claims 1, 5, 7, and 9-18 which were rejected under 35 U.S.C. § 103(a) as being obvious over Thoren in view of Helland and in view of Macgregor (U.S. 4,280,514).

Claims 1, 5, 7, 9, and 10

Appellant traverses the obviousness rejection of claim 1. Appellant believes claim 1 is not obvious in view of the cited references since, even if combined, the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the cited combination: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1.

As discussed above, Thoren discusses a lead with a side component 5 which is receptive to tissue ingrowth, and Helland discusses a lead with the electrode tip having spheroidal particles 70 for chronic ingrowth of tissue. (Col. 6, lines 5-8). The MacGregor reference also does not discuss anything to do with a lead body and does not overcome the deficiencies of the Thoren and Helland references discussed above. Accordingly, the combination does not suggest or include "a lead body adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream," as recited in claim 1.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 11-16

Appellant believes claim 11 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the combination: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11.

As discussed above, the references, both singly and in combination, do not include such subject matter.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 17 and 18

Appellant believes claim 17 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the combination: wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17.

As discussed above, the references, both singly and in combination, do not include such subject matter.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

SUMMARY

For the reasons argued above, the pending claims were not properly rejected.

It is respectfully submitted that the art cited does not render the claims obvious and that the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claim are respectfully requested.

Respectfully submitted,

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Date December 8, 2009 By /Peter C. Maki/
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 8th day of December 2009.

Nellie Nuhring
Name

/Nellie Nuhring/
Signature

8. CLAIMS APPENDIX

1. A lead comprising:

a lead body extending from a proximal end to a distal end; and

a ring electrode coupled to the lead body;

wherein the lead body and the ring electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, and wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres.

2. The lead of claim 1, wherein the outer surface of the lead is textured so as to form a pseudo-intimal layer on the outer surface.

3. The lead of claim 1, wherein the lead body includes at least a portion seeded with endothelial cells or stem cells.

4. The lead of claim 1, wherein the lead body material includes a phospholipid polymer.

5. The lead of claim 1, wherein the titanium microspheres have a diameter of between 75-100 μm.

7. The lead of claim 1, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent blood cell layer.

8. The lead of claim 1, wherein the lead body includes an amino acid sequence attached to a polymer, the amino acid sequence chosen to bind to cell receptors.

9. The lead of claim 1, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

10. The lead of claim 1, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

11. A lead comprising:

a lead body extending from a proximal end to a distal end; and

a ring electrode coupled to the lead body;

wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; and

wherein the ring electrode includes an outer textured surface including titanium microspheres.

12. The lead of claim 11, wherein the electrode outer surface is adapted to trap blood cells within the textured surface to form a layer of blood cells on the electrode surface.

13. The lead of claim 11, wherein the titanium microspheres have a diameter of between 75-100 μm.

14. The lead of claim 11, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

15. The lead of claim 11, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

16. The lead of claim 11, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

17. A lead comprising:

a lead body extending from a proximal end to a distal end;

a ring electrode coupled to the lead body; and

means for passively preventing formation of clots on the ring electrode and the lead body, wherein means for passively preventing clots on the ring electrode includes a titanium microsphere outer surface coating on at least a portion of the ring electrode, and wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream.

18. The lead of claim 17, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

19. The lead of claim 17, wherein means for passively preventing includes at least a portion of the lead body having an outer surface seeded with endothelial cells or stem cells.

20. The lead of claim 17, wherein means for passively preventing includes the lead body having an outer surface including a phospholipid polymer material.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.